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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

FRANCIS FENWICK, et al.,	:	CIVIL ACTION NO.:
	:	3:12-cv-07354-PGS-DEA
Plaintiffs,	:	
	:	
vs.	:	
	:	
RANBAXY PHARMACEUTICALS, INC., et al.,	:	
	:	
	:	
Defendants.	:	

BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION BY DEFENDANTS EXPRESS SCRIPTS, INC., EXPRESS SCRIPTS HOLDING COMPANY AND MEDCO HEALTH SOLUTIONS, INC.

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COME NOW Defendants Express Scripts, Inc., Express Scripts Holding Company and Medco Health Solutions, Inc. (collectively referred to as the "Express Scripts Defendants" for purposes of this Brief only),[1] and for their opposition to Plaintiffs' Motion for Preliminary Injunction (Doc. #15) state as follows:

I. INTRODUCTION

This case arises from the separate defendant Ranbaxy Pharmaceuticals Inc.'s November 2012 voluntary recall of certain lots of the prescription drug atorvastatin. Ranbaxy recalled 41 specific lots of atorvastatin due to possible contamination with very small glass particles, similar to the size of a grain of sand (less than 1 mm in size). The U.S. Food and Drug Administration ("FDA") is currently overseeing the recall process.

The FDA has indicated that the "possibility of adverse health problems related to the recalled atorvastatin is extremely low" and that "[p]atients who have the recalled medicine can continue taking it unless directed otherwise by their physician or health care provider."[2] The recall extends only to the retail

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[1] Express Scripts, Inc., Express Scripts Holding Company and Medco Health Solutions, Inc. are three separate companies. However, Plaintiffs refer to them collectively as "Express Scripts" throughout the Second Amended Complaint. Second Amended Complaint, at ¶ 19.

[2] *See* "FDA Statement on the Ranbaxy Atorvastatin Recall," (Update 11/30/2012); http://www.fda.gov/Drugs/DrugSafety/ucm329951.htm. A print-out of the FDA's statement is attached as Exhibit A to the Declaration of Alan S. Naar, Esq. filed contemporaneously herewith.

(pharmacy) level, not to the consumer level. A retail level recall requires pharmacies to quarantine any recalled lots and cease dispensing from those lots as of the time of the recall notification. There is no requirement to determine if patients have received tablets from the recalled lots of product.

Plaintiffs have filed this lawsuit asking the Court to issue a preliminary injunction mandating that the recall be extended to the consumer/patient level – *i.e.*, a "total product recall."[3] However, Congress has vested the FDA with the authority to monitor and supervise recalls. The FDA regulations require the FDA, *inter alia*, to determine the scope of the recall (*e.g.*, retail versus consumer level) and evaluate the adequacy and extent of any recall communications or public warnings.

As a result, the relief Plaintiffs seek is precluded by the primary jurisdiction doctrine. Because Congress has vested the FDA with authority to determine the scope and adequacy of the recall, this Court cannot issue a preliminary injunction mandating a consumer-level recall. Moreover, Plaintiffs' request would force the Court to engage in its own independent scientific and medical analyses on issues best left to the expertise of the FDA.

Although it is clear that the primary jurisdiction doctrine bars the relief sought, should the Court consider the merits of Plaintiffs' Motion, the Motion

[3] The relief sought by Plaintiffs is far-reaching and would impact thousands of pharmacies located across the United States.

should be denied. First, all of Plaintiffs' claims against the Express Scripts Defendants are based upon the faulty premise that "Express Scripts" is a pharmacy and sold two of the plaintiffs (Edward Safran and Steve Harding) tablets from lots of atorvastatin subject to the recall. In reality, none of the Express Scripts Defendants are pharmacies, and none sold Safran or Harding atorvastatin tablets. *See* Declaration of Douglas R. Lang, at ¶¶ 3, 5-6, filed contemporaneously herewith. For this reason alone, the requested relief against the Express Scripts Defendants must fail.

Moreover, Plaintiffs have failed to meet their burden of establishing any right to injunctive relief. First, the Motion fails to identify any valid cause of action upon which Plaintiffs are likely to succeed. Second, Plaintiffs fail to identify any irreparable or imminent harm; in fact, as of the date of this Brief, there is no evidence that Plaintiffs (or anyone else) cannot obtain atorvastatin from lots not affected by the recall. Moreover, none of the Plaintiffs have established that the atorvastatin tablets he or she received actually contain foreign material. At best, Plaintiffs complain only of past harm which can be adequately addressed by monetary damages if they ultimately prove their underlying claims. Finally, the Motion should be denied because it is "supported" only by unsworn written statements, hearsay quoted from newspaper articles, and unqualified medical speculation and conjecture.

II. FACTUAL BACKGROUND

In November 2012, the Ranbaxy Defendants[4] initiated a voluntary recall of specific lots of the prescription drug atorvastatin that may contain very small glass particles. Second Amended Complaint, at ¶¶ 1, 27-28, 36. The scope of the recall extends to the "retail level only," meaning to pharmacies, and not to consumers like Plaintiffs. *Id.*, at ¶¶ 28-29, 31, 36-38. The recall does not request or require pharmacies to provide notice to consumers, nor does it require pharmacies to offer replacement tablets and/or refunds to consumers who have already purchased tablets dispensed from the recalled lots. *Id.*, at ¶ 28-29, 31, 37-38, 40. The Ranbaxy Defendants' website states that "the recall is being conducted with the full knowledge of the U.S. FDA" and provides electronic links to the FDA's website.[5] *Id.*, at ¶ 36.

The FDA's website states that the FDA has determined that "[t]he possibility of adverse health problems related to the recalled atorvastatin is extremely low" and "[p]atients who have the recalled medicine can continue taking it unless

[4] The Ranbaxy Defendants' website indicates the recall is being conducted by Ranbaxy Pharmaceuticals, Inc., but Plaintiffs lump all of the "Ranbaxy Defendants" together in the Second Amended Complaint. Second Amended Complaint, at ¶ 11.

[5] *See* http://www.ranbaxyusa.com.

directed otherwise by their physician or health care provider."[6] The FDA also advises that it "will continue to oversee the recall process and work with Ranbaxy to resolve quality issues." The FDA has not required a consumer level recall.

Plaintiffs do not allege that the Express Scripts Defendants failed to comply with the recall.[7] Instead, Plaintiffs argue that the Express Scripts Defendants must expand the scope of the atorvastatin recall currently being conducted by Ranbaxy and overseen by the FDA by escalating it to the consumer level, notifying individual consumers and offering refunds or replacements. Plaintiffs essentially ask this Court to second-guess the FDA's expertise and authority and order Ranbaxy and the Express Scripts Defendants to conduct a "total" recall. As discussed below, such relief is improper and Plaintiffs' Motion for injunctive relief should be denied.

III. LEGAL ANALYSIS

A. PLAINTIFFS' MOTION MUST BE DENIED PURSUANT TO THE PRIMARY JURISDICTION DOCTRINE

Plaintiffs ask this Court to override the scope of the current recall being overseen by the FDA and put in place a court-mandated "total" product recall.

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[6] *See* "FDA Statement on the Ranbaxy Atorvastatin Recall" (update 11/30/2012) available at http://www.fda.gov/Drugs/DrugSafety/ucm329951.htm and attached as Exhibit A to Alan S. Naar, Esq.'s Declaration.

[7] Plaintiffs Safran and Harding are the only plaintiffs who allege they purchased atorvastatin from the Express Scripts Defendants. As such, no other plaintiff has alleged any basis for a claim against the Express Scripts Defendants.

Such action is barred by the primary jurisdiction doctrine because "Plaintiffs are essentially asking the Court to perform the tasks traditionally relegated to the FDA." *See In re Human Tissue Prods. Liability Litig.*, 488 F. Supp. 2d 430, 433 (D. N.J. 2007); *Clark v. Actavis Group HF*, 567 F. Supp. 2d 711 (D. N.J. 2008). "Congress vested the FDA with the authority to monitor and supervise product recalls," and the primary jurisdiction doctrine requires the Court to "defer to the exclusive competence of that agency." *Clark*, 567 F. Supp. 2d at 715 (citing *Human Tissue*, 488 F. Supp. 2d at 432).

In denying a similar request for injunctive relief in *Clark*, Judge Greenaway stated:

> The doctrine of primary jurisdiction allows a federal court to refer a matter extending beyond the conventional experience of judges or falling within the realm of administrative discretion to an administrative agency with more specialized experience, expertise, and insight. Specifically, courts apply primary jurisdiction to cases involving technical and intricate questions of fact and policy that Congress has assigned to a specific agency.

Clark, 567 F. Supp. 2d at 715 (citations omitted). *See also MCI Tele. Corp. v. Teleconcepts, Inc.*, 71 F.3d 1086, 1103 (3d Cir. 1995) ("If a legislature has vested an administrative agency with exclusive primary jurisdiction, that agency is the only forum in which complaints within that jurisdiction may be brought."); *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 654 (1973); *U.S. v. Western Pacific RR Co.*, 352 U.S. 59 (1956).

The decisions in *Clark* and *Human Tissue* are directly on point. In *Human Tissue*, plaintiffs sought an order requiring an updated notice be sent to absent class members concerning the need to have a blood test as a result of receiving unscreened tissue. 488 F. Supp. 2d at 431. Judge Martini held that the doctrine of primary jurisdiction precluded the relief plaintiffs sought, because Congress "vest[ed] the FDA with the authority to monitor and supervise product recalls." *Id.* at 432. The Court held that matters concerning the formulation of a recall strategy, including the scope or "depth" of a recall and adequacy of notice, are "best left to the FDA's considered competence in these matters." *Id.*

In *Clark*, the FDA had announced a recall of the prescription drug Digitek®, which was manufactured by the defendants. 567 F. Supp. 2d at 712. That recall required that specific notice be provided to consumers. *Id.* at 716. Plaintiff consumers brought suit asking the Court to order defendants to issue an additional notice to consumers, beyond that which was already approved by the FDA. *Id.* at 714. The Court declined to do so, holding that "[b]y requesting the Court to issue a similar notice here, Plaintiffs are essentially asking the Court to perform the tasks traditionally relegated to the FDA." *Clark*, 567 F. Supp. 2d 717 (quoting *Human Tissue*, 488 F. Supp. 2d at 433).

The Courts in *Clark* and *Human Tissue* recognized the breadth of the FDA's regulatory authority with respect to determining appropriate recall procedures for

pharmaceutical products, as set forth in 21 C.F.R. § 7.40-7.59:

- "An ad hoc committee of FDA scientists evaluates health hazards associated with the product being recalled, and then determines the classification to assign to the recall." *Clark*, 567 F. Supp. 2d 717 (quoting *Human Tissue*, 488 F. Supp. 2d at 432 (citing 21 C.F.R. §§ 7.41(a)-(b)).
- The FDA "review[s] the adequacy of a proposed recall strategy developed by a recalling firm and recommend[s] changes as appropriate." *Id.* (citing 21 C.F.R. §§ 7.42(a)).
- The "FDA assumes control over monitoring recalls and assesses the adequacy of a firm's efforts in undertaking the recall." *Id.* (citing 21 C.F.R. §§ 7.40-7.59).
- The FDA regulations "require the FDA to evaluate . . . the adequacy and extent of recall communications." *Human Tissue*, 488 F. Supp. 2d at 432-33 (citing 21 C.F.R. § § 7.41-7.42).
- The FDA regulations require a determination of "the 'depth of the recall' and the content of a public warning." *Id.* (citing 21 C.F.R. § 7.42(b)(1)-(2)).
- The "FDA determines when the recall will be terminated." *Id.* (citing 21 C.F.R. § 7.55(a)).

A key aspect of a recall strategy is the "depth" of the recall, meaning the "level in the distribution chain to which the recall is to extend." 21 C.F.R.

§ 7.42(b)(1). "Depending on the product's degree of hazard and extent of distribution," the FDA must determine whether the recall should extend to the (i) Consumer level, (ii) Retail level, or (iii) Wholesale level. *Id.* Here, the FDA has determined that the recall of atorvastatin at the retail level is appropriate. Plaintiffs ask this Court to second-guess this determination and issue an order mandating "a total product recall" extending to the consumer level. Under the primary jurisdiction doctrine, the Court should not interfere with the FDA's determination of the "depth" of the recall. *Human Tissue*, 488 F. Supp. 2d 430.

Plaintiffs' claims and requested relief would "require[] this Court to engage in the type of technical analysis conducted by the FDA." *Clark,* 567 F. Supp. 2d at 717. To issue the injunction requested by Plaintiffs, this Court would need to analyze complex medical issues and scientific data – including the probability that particular batches of atorvastatin actually contained glass particles; the risk that ingesting a recalled product would actually cause an adverse health effect to an individual; the severity of that potential health risk; and other public health considerations. Such "intense medical analysis" is outside the conventional experience of the courts and "clearly lies within the realm of the FDA's authority." *Clark*, 567 F. Supp. 2d at 716, 718; *Human Tissue*, 488 F. Supp. 2d at 433.

Further, the injunction sought by Plaintiffs could actually interfere with the recall and create conflicting obligations. As the Court in *Clark* found, "the relief

[plaintiffs] seek would interfere with the FDA's recall, as the FDA had continued authority to monitor recalls and assess the adequacy of a firm's efforts in recall." 567 F. Supp. 2d at 718. Here, the FDA has already issued notice to the public that "[p]atients who have the recalled medicine can continue taking it unless directed otherwise by their physician or health care provider." *See* FDA Website, *supra*. Plaintiffs now ask this Court to order a contrary notice to consumers advising them not to take the medicine and to return it for replacement and/or refund. The relief sought by Plaintiffs "could create a potentially dangerous situation" because it would require "inconsistent notices being sent" to consumers. *Human Tissue*, 488 F. Supp. 2d at 433.

If Plaintiffs believe that they have additional information on the alleged health effects of atorvastatin, they are free to present it to the FDA for consideration. *See Clark*, 567 F. Supp. 2d at 719. However, to the extent that the FDA has already determined that a retail level recall is appropriate, "that agency's determination is binding upon the court and the parties" and "is not subject to collateral attack" by the courts. *MCI Tele.*, 71 F.3d at 1103 (citations omitted).

Just as in *Clark* and *Human Tissue*, the primary jurisdiction doctrine bars the injunctive relief Plaintiffs seek. Plaintiffs ask the Court to override the FDA's expertise and authority and order new notice requirements, and to judicially implement a recall to the consumer level. This Court should decline to do so and

deny Plaintiffs' request for a preliminary injunction.

B. PLAINTIFFS HAVE FAILED TO MEET THE REQUIREMENTS FOR OBTAINING A PRELIMINARY INJUNCTION

Even if the Court were to analyze the merits of Plaintiffs' Motion, Plaintiffs have failed to meet their burden for obtaining the extraordinary relief they seek. "[T]he grant of injunctive relief is an extraordinary remedy . . . which should be granted only in limited circumstances." *AT & T v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1426 (3d Cir.1994). In cases like this where a party moves for a mandatory preliminary injunction that would "disturb the status quo" and provide the moving party with "substantially all the relief he may recover at the conclusion of a full trial on the merits," courts apply "heightened scrutiny" to such motions. *Black Mountain Equities, Inc. v. Pacific Gold Corp.*, No. 2:12-CV-01285 (KM), 2012 WL 5986488, at *4 (D. N.J. Nov. 27, 2012). Indeed, as the parties seeking a mandatory preliminary injunction that would upset the status quo, Plaintiffs bear the "particularly heavy burden in demonstrating its necessity." *Acierno v. New Castle County*, 40 F.3d 645, 653 (3d Cir. 1994). While Plaintiffs characterize the relief they seek as "preliminary" in nature, in reality it would be "permanent" as there is no way to "undo" an expanded recall to the consumer level once it occurs. Thus, heightened scrutiny is necessary here.

A court must consider four factors when ruling on a motion for preliminary injunction: "(1) whether the movant has shown a reasonable probability of success

on the merits; (2) whether the movant will be irreparably injured by denial of the relief; (3) whether granting preliminary relief will result in even greater harm to the nonmoving party; and (4) whether granting preliminary relief will be in the public interest." *American Exp. Travel Related Services, Inc. v. Sidamon-Eristoff*, 669 F.3d 359, 366 (3d Cir. 2012).

While a court should consider all four factors, "the first two are essential: A court may not grant injunctive relief, 'regardless of what the equities seem to require,' unless plaintiffs carry their burden of establishing *both* a likelihood of success and irreparable harm." *Aleynikov v. Goldman Sachs Group, Inc.*, Civ. No. 12–5994 (KM), 2012 WL 6603397, at *3 (D. N.J. Dec. 14, 2012) (emphasis original) (citing *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 484 (3d Cir.2000)).

As demonstrated below, Plaintiffs do not come close to meeting their high burden.

1. Plaintiffs have not demonstrated a likelihood of success on the merits.

"The moving party's failure to show a likelihood of success on the merits must necessarily result in the denial of a preliminary injunction." *American Exp. Travel Related Services*, 669 F.3d at 366 (citation omitted); *see also Black Mountain Equities*, 2012 WL 5986488, at *4 ("Failure to establish a likelihood of success on the merits, even standing alone, is fatal to an application for a preliminary injunction."). Here, Plaintiffs have put the cart before the horse; they

have identified the remedy they seek – a "total" product recall – without identifying ***any*** cause of action contained in the Second Amended Complaint that, if proven, would entitle them to such relief.[8]

Instead, Plaintiffs simply proclaim that "it is highly likely that [they] will succeed on the merits of their case." Memo of Law (Doc. #15-4), at p. 6. This conclusory statement does not come close to meeting Plaintiffs' burden "to prove that they were likely to succeed on the merits of their claim." *See P.C. Yonkers, Inc. v. Celebrations The Party & Seasonal Superstore, LLC*, 428 F.3d 504, 508, 510 (3d Cir. 2005) (affirming district court's holding that "plaintiffs' proffer was not sufficient and that due to the speculative nature of their proof, they failed to demonstrate that they could succeed on the merits of any of their claims so as to warrant injunctive relief").[9] Here, when Plaintiffs have made no attempt to even *address* the merits of their claims, a grant of injunctive relief cannot lie.[10]

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[8] A claim for "injunctive relief" is a "remedy, not an independent cause of action." *Volunteer Firemen's Ins. Servs., Inc. v. Fuller*, No. 1:12-CV-2016, 2012 WL 6681802, at *12 (M.D. Pa. Dec. 21, 2012) (citing *Tolia v. Dunkin Brands*, 2011 WL 6132102 (D. N.J. Oct. 7, 2011) (collecting cases)).

[9] Moreover, while Plaintiffs have not even addressed the claims that are asserted in their Second Amended Complaint, Plaintiffs cannot demonstrate any likelihood of succeeding on any of the claims asserted, as set forth in Defendants' Motion to Dismiss Plaintiffs' Second Amended Complaint to be filed on March 5, 2013.

[10] Plaintiffs' Motion contains reference to a section of the federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 351, which defines the term "adulterated." Doc. #15-4, at p. 5. However, Plaintiffs' reference to the FDCA does not support a

In sum, Plaintiffs have not even attempted to demonstrate any likelihood of success on any claim. This alone requires the Court to deny their Motion.

2. Plaintiffs cannot establish irreparable injury.

As Plaintiffs acknowledge, "[i]n this Circuit, irreparable injury has been defined as 'potential harm which cannot be redressed by a legal or an equitable remedy following a trial.'" Doc. # 15-4 at 6 (quoting *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 801 (3d Cir. 1989) (reversing grant of preliminary injunction because the plaintiff failed to establish irreparable injury)). The Third Circuit has "repeatedly insisted that . . . the preliminary injunction device should not be exercised unless the moving party shows that it specifically and personally risks irreparable harm." *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 487 (3d Cir. 2000). "The key word in this consideration is *irreparable.* Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of [an injunction], are not enough. . . . [T]he injury created by a failure to issue the requested injunction must 'be of a peculiar nature, so that compensation in money cannot atone for it.'" *Acierno*, 40 F.3d at 653 (citations omitted). *See also Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882

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preliminary injunction, because Plaintiffs' Second Amended Complaint does not contain a claim under the FDCA. Nor could it: "It is . . . well established that Congress has not created an express or implied private cause of action for violations of the FDCA." *See, e.g., In re Orthopedic Bone Screw Prods. Liability Litig.*, 159 F.3d 817, 824 (3d Cir. 1998); *see also* 21 U.S.C. § 337(a) (restricting FDCA enforcement to suits by the United States).

F.2d 797, 801 (3d Cir. 1989) ("In order to demonstrate irreparable harm the plaintiff must demonstrate potential harm which cannot be redressed by a legal or an equitable remedy following a trial. The preliminary injunction must be the only way of protecting the plaintiff from harm.").

a. The FDA has already concluded that the risk of harm is "extremely low."

The FDA already has concluded that "the possibility of adverse health problems related to the recalled atorvastatin is extremely low." *See* Ex. D to Plaintiff's Motion, Doc. # 15-2 at p. 13 (emphasis added). Indeed, the FDA has directed consumers who received the recalled medicine to continue taking it. This determination is dispositive, and the Court need look no further or attempt to balance the FDA's expert analysis with the Plaintiffs' lawyer's summary of telephone calls and news articles.

b. No irreparable harm exists because Plaintiffs with a valid prescription can obtain atorvastatin and/or seek monetary damages.

Plaintiffs will suffer no irreparable harm absent injunctive relief because supplies of atorvastatin from batches not subject to the recall are available. Plaintiffs have thus failed to demonstrate how an injunction could provide any necessary relief or is "the only way of protecting the plaintiff[s] from harm." *Instant Air Freight*, 882 F.2d at 801.

Moreover, to the extent any plaintiff could demonstrate and prove he or she suffered damages associated with the allegedly "tainted" atorvastatin, monetary damages would provide an adequate remedy for this past harm. "If money damages will provide an adequate remedy to Plaintiffs, there is no irreparable harm, so equitable relief cannot be issued." *Rosso v. Daimler Chrysler Corp.*, 2008 WL 185497, at * 7 (D. N.J. Jan. 18, 2008); *see also Frank's GMC Truck Center, Inc. v. General Motors Corp.*, 847 F.2d 100, 102 (3d Cir. 1988) ("The availability of adequate monetary damages belies a claim of irreparable injury.").

c. No individual Plaintiff has demonstrated irreparable harm.

Only two plaintiffs, Safran and Harding, purport to have a claim against the Express Scripts Defendants. Those two, as well as the other four "declarants," have not demonstrated that they face any irreparable harm.

Plaintiffs' "Declarations" are not made under penalty of perjury, and thus are not competent evidence. But even if the Court were to consider them, they fall woefully short of establishing the need for injunctive relief. For example:

- None of the Plaintiffs offer any proof that the atorvastatin tablets they received actually had any glass in them.
- None of the Plaintiffs claim to have ever missed a dose of medication.
- Safran does not allege that he ever ingested any "tainted" atorvastatin or suffered any physical illness or injuries.

- Harding claims to have suffered temporary physical symptoms (loose stools and frequent diarrhea) but admits that his "blood pressure and bowel movements eventually returned to normal . . ."
- Those that claim to have suffered physical symptoms (Harding, Young and Richards) offer no "evidence," other than self-serving "Declarations," that any of their alleged symptoms were proximately caused by taking "tainted" atorvastatin.
- Three of the plaintiffs (Wardrett, McCall and Richards) admit that they have already received replacement medicine.

Most of the remaining exhibits attached to Plaintiffs' Motion are nothing more than newspaper articles that report on the status of the recall and predate the FDA's November 30, 2012 statements on its website. They offer no independent evidence to support a grant of extraordinary relief in the form of an injunction overriding the current scope of the recall overseen by the FDA.

i. Safran has not presented any evidence of irreparable (or any) harm.

In his unsworn written statement, Safran claims that he received the recalled product on October 10, 2012 and that he learned the pills were "from a tainted lot" on November 28, 2012. Safran "Declaration," Doc. # 15-2 at p. 28, ¶¶ 3-5. Safran also claims that he was "afraid that ingesting the tainted pills could cause injury" and that he was "concerned and/or fearful that [his] health would suffer from a lack

of [atorvastatin]." *Id.*, at p. 29, ¶ 7.

Although Safran claims he was "fearful," Safran does *not* claim that he ever actually missed or has been without a single dose of atorvastatin. Safran also does *not* claim that he ever ingested the allegedly "tainted" tablets. Most importantly, Safran received a prescription fill of atorvastatin not affected by the recall on or about December 5, 2012. *See* Declaration of Douglas Lang, at ¶ 5. Thus, to the extent Safran could ever claim he was concerned about a "lack of" atorvastatin, such concern would have been alleviated shortly after December 5, 2012, well before he joined this lawsuit on December 10, 2012 (*see* Am. Compl., Doc. # 3), and certainly well before he signed his written statement on January 24, 2013. *See* Safran "Declaration," Doc. # 15-2 at p. 29.

ii. Harding admits that he currently suffers no irreparable harm.

Harding claims he received the recalled product on October 18, 2012. Harding "Declaration," Doc. # 15-2, at p. 30, ¶¶ 3, 4. He also claims that he "took the pills every day from the time [he] filled the prescription until [he] found out about the recall." *Id.*, at p. 31, ¶ 7. Harding claims that he experienced medical problems and/or adverse health effects ("loose stools" and "frequent diarrhea") during the time period in which he took the pills. *Id.* However, Harding presents no medical or expert evidence demonstrating that any of his alleged medical problems were caused by atorvastatin. Moreover, Harding admits his health has

"returned to normal." *Id.*

Harding's alleged harm already has occurred and, by his own admission, is not continuing. Plaintiffs cannot make a "clear showing of *immediate* irreparable harm" when the act to be enjoined already has occurred and all that remains is "past harm." *Campbell Soup Co. v. ConAgra, Inc.*, 977 F.2d 86, 91-92 (3d Cir. 1992) (reversing district court's entry of preliminary injunction, holding "[w]e fail to see how immediate irreparable harm could arise at this time" when the threatened disclosure had already occurred).

iii. The other plaintiffs present no evidence of irreparable harm.

The remaining "declarations," those of Mary Wardrett, Linda Young, Lisa McCall and Constance Richards, do not relate to any alleged action or omission by the Express Scripts Defendants. However, to the extent the Court considers them in ruling on the instant Motion, they offer no evidence of irreparable harm.

For example, the written statements of Wardrett and McCall actually admit the two women received a replacement bottle of atorvastatin – the very relief Plaintiffs' Motion seeks. Wardrett "Declaration," Doc. # 15-2, at p. 32, ¶ 4; McCall "Declaration," Doc. # 15-2, at p. 36, ¶ 4. These statements refute any claim that a preliminary injunction is necessary to prevent irreparable harm.

Moreover, like Harding's statements, the statements in the declarations of Wardrett, Young and Richards relating to alleged injuries are simply non-expert,

self-diagnosed statements about unverified medical problems and purport to connect the recalled product to these medical problems without any foundation.[11] Wardrett "Declaration," Doc. # 15-2, at p. 32, ¶ 6; Young "Declaration," Doc. # 15-2, at p. 34, ¶ 6; Richards "Declaration," Doc. # 15-2, at p. 39, ¶ 6. These "declarations" are insufficient to support a grant of preliminary injunction.

d. Plaintiffs have presented no evidence that irreparable harm will be suffered on a class-wide basis so as to warrant mass preliminary injunctive relief.

Notwithstanding the named Plaintiffs' own failure to demonstrate irreparable harm, they seek an injunction on a class-wide basis. However, as the Third Circuit has stated, "[i]n the absence of a foundation from which one could infer that all (or virtually all) members of a group are irreparably harmed, we do not believe that a court can enter a mass preliminary injunction." *Adams*, 204 F.3d at 487. Accordingly, where no evidence is presented that potential class members have suffered or could face irreparable injury, a class-wide preliminary injunction is improper. *Id.* Moreover, Plaintiffs' request for class-wide relief is improper, as Plaintiffs will not be able to establish the requirements for class certification under Federal Rule of Civil Procedure 23, given the plethora of individual issues regarding each putative class member's particular circumstances.

[11] Wardrett's "Declaration" is not even signed.

As stated above, the six "Declarations" submitted by Plaintiffs do not provide competent evidence that the named Plaintiffs will suffer irreparable harm absent injunctive relief – much less demonstrate how irreparable injury would occur to the putative class absent injunctive relief. Rather, without citing any legal authority, Plaintiffs simply claim that class members will be irreparably harmed by the "looming possibility of injury . . . caused by ingesting the defendants' adulterated product." Plaintiffs' Motion, Doc. # 15-4, at 6. With respect to these absent, unidentified people the only thing Plaintiffs offer is a news reporter's statement that one patient *complained of* an injury, and Plaintiffs' lawyer's hearsay statement that he called "more than 35 consumers" and that "many complained about physical problems." *See id.*, at 7; "Gainey Declaration," Doc. # 15-1, at ¶15. However, "[a] preliminary injunction may not be based on facts . . . not presented through affidavits, deposition testimony, or other documents, about the particular situations of the moving parties." *Adams*, 204 F.3d at 487.

"[T]he demanding requirements for a preliminary injunction do not yield to numbers." *Adams*, 204 F.3d at 487. Plaintiffs have failed to provide any support for why a preliminary injunction is necessary on a class-wide basis.

3. Balance of Equities

Because Plaintiffs have failed to demonstrate a likelihood of success on the merits and irreparable harm, the Court need not even consider the final two factors.

See, e.g., In re Pagano Development Co., Inc., No. 11–4448 (FSH), 2011 WL 5082203, at * 4 (D. N.J. Oct. 25, 2011).

Nonetheless, in balancing the equities between the parties, it is clear that this factor weighs against entering an injunction. If this Court enters an order effectively altering the current recall being overseen by the FDA, the Express Scripts Defendants will be faced with the predicament of having to comply with two competing directives. Moreover, as explained above, Plaintiffs do not face great harm absent an injunction. The FDA has determined that the current recall procedures are sufficient, and there is no evidence that consumers will suffer any harm or that they are not currently able to obtain sufficient supplies of their medication from lots not affected by the recall (including lots made by other generic drug manufacturers).

4. Public Interest

Finally, in this case, the public interest is already reflected in the current recall procedures authorized and overseen by the FDA and the public statements by the FDA that consumers who received atorvastatin should continue to take it. Indeed, the purpose of the FDA-monitored recall policy is to "protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective." 21 C.F.R. § 7.40(a). Contrary to Plaintiffs' speculation, it is in the public's best interest to defer to the FDA's expert judgment

regarding the parameters of the recall and not to alter it based on news articles, conjecture and speculation. Accordingly, this factor weighs heavily in favor of maintaining the status quo of the current recall procedures in place, and against entering a preliminary injunction.

IV. CONCLUSION

WHEREFORE, Defendants Express Scripts, Inc., Express Scripts Holding Company and Medco Health Solutions, Inc. respectfully request that the Court deny Plaintiffs' Motion for Preliminary Injunction, with prejudice, and award them such other and further relief as the Court deems just and proper.

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing "BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION BY DEFENDANTS EXPRESS SCRIPTS, INC., EXPRESS SCRIPTS HOLDING COMPANY AND MEDCO HEALTH SOLUTIONS, INC." has been served on counsel of record by the Court's ECF filing system on this 19th day of February, 2013.

s/Alan S. Naar